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510(k) SUMMARY

510(k) Owner:	Alfa Wassermann Diagnostic Technologies, LLC 4 Henderson Drive West Caldwell, NJ 07006 Contact: Hyman Katz, Ph.D. Phone: 973-852-0158 Fax: 973-852-0237	
Date Summary Updated:	March 29, 2012	
Device:	Trade Name: System	ACE Axcel Clinical Chemistry
	Classification:	Class 1
	Common/Classification Name:	Analyzer, Chemistry (Photometric, Discrete), For Clinical Use (21 C.F.R. § 862.2610) Product Code JJE
	Trade Name:	ACE Direct Total Iron-Binding Capacity (TIBC) Reagent
	Classification:	Class 1
	Common/Classification Name:	Direct Total Iron-Binding Capacity (TIBC) (21 C.F.R. § 862.1415) Product Code JMO
	Trade Name:	ACE Serum Iron Reagent
	Classification:	Class 1
	Common/Classification Name:	Photometric Method, Iron (Non-Heme) (21 C.F.R. § 862.1410) Product Code JIY
	Trade Name:	ACE Lipase Reagent
	Classification:	Class 1
	Common/Classification Name:	Lipase-Esterase, Enzymatic, Photometric, Lipase (21 C.F.R. § 862.1465)

	Product Code CHI
Predicate Devices:	Manufacturer for analyzer/reagent system predicate: Alfa Wassermann ACE Clinical Chemistry System (K931786) ACE Reagents (K000781, K944911)
Device Descriptions:	The ACE Axcel Clinical Chemistry System consists of two major components, the chemistry instrument and an integrated Panel PC. The instrument accepts the physical patient samples, performs the appropriate optical or potentiometric measurements on those samples and communicates that data to an integral Panel PC. The Panel PC uses keyboard or touch screen input to manually enter a variety of data, control and accept data from the instrument, manage and maintain system information and generate reports relative to patient status and instrument performance. The Panel PC also allows remote download of patient requisitions and upload of patient results via a standard interface. In the ACE Direct Total Iron-Binding Capacity (TIBC) Reagent assay, Direct TIBC Color Reagent, an acidic buffer containing an iron-binding dye and ferric chloride, is added to the serum sample. The low pH of Direct TIBC Color Reagent releases iron from transferrin. The iron then forms a colored complex with the dye. The colored complex at the end of the first step represents both the serum iron and excess iron already present in Direct TIBC Color Reagent. Direct TIBC Buffer, a neutral buffer, is then added, shifting the pH and resulting in a large increase in the affinity of transferrin for iron. The serum transferrin rapidly binds the iron by abstracting it from the dye-iron complex. The observed decrease in absorbance of the colored dye-iron complex is directly proportional to the total iron-binding capacity of the serum sample. The absorbance is measured at 647 nm. In the ACE Serum Iron Reagent assay, transferrin-bound iron in serum is released at an acidic pH and reduced from ferric to ferrous ions. These ions react with ferrozine to form a violet colored complex, which is measured bichromatically at 554 nm/692 nm. The intensity of color produced is directly proportional to the serum iron concentration. In the ACE Lipase Reagent Assay, serum lipase acts on a natural substrate, 1,2-diglyceride, to liberate 2-monoglyceride. This is hydrolyzed by monoglyceride lipase (a highly specific enzyme for monoglyceride) into glycerol and free fatty acid. Glycerol kinase acts on glycerol to form glycerol-3-phosphate, which is in turn acted on by glycerol-3-phosphate oxidase to generate hydrogen peroxide. Peroxidase converts the hydrogen peroxide, 4-Aminoantipyrine and TOOS (N-ethyl-N-(2-hydroxy-3-sulfopropyl)-m-toluidine) into a quinine dye. The rate of formation of the dye, determined

	bichromatically at an absorbance of 573 nm/692 nm, is proportional to the lipase activity in the sample.
Intended Use:	Indications for Use: The ACE Axcel Clinical Chemistry System is an automated, discrete, bench-top, random access analyzer that is intended for *in vitro* diagnostic use in the quantitative determination of constituents in blood and other fluids. The ACE TIBC Reagent is intended for the quantitative determination of total iron-binding capacity in serum using the ACE Axcel Clinical Chemistry System. Iron-binding capacity measurements are used in the diagnosis and treatment of anemia. This test is intended for use in clinical laboratories or physician office laboratories. For in vitro diagnostic use only. The ACE Serum Iron Reagent is intended for the quantitative determination of iron concentration in serum using the ACE Axcel Clinical Chemistry System. Iron (non-heme) measurements are used in the diagnosis and treatment of diseases such as iron deficiency anemia, hemochromatosis (a disease associated with widespread deposit in the tissues of two iron-containing pigments, hemosiderin and hemofuscin, and characterized by pigmentation of the skin), and chronic renal disease. This test is intended for use in clinical laboratories or physician office laboratories. For in vitro diagnostic use only. The ACE Lipase Reagent is intended for the quantitative determination of lipase activity in serum using the ACE Axcel Clinical Chemistry System. Lipase measurements are used in diagnosis and treatment of diseases of the pancreas such as acute pancreatitis and obstruction of the pancreatic duct. This test is intended for use in clinical laboratories or physician office laboratories. For in vitro diagnostic use only.
Technological Characteristics:	The following is a description of the major features of the ACE Axcel Clinical Chemistry System: - System throughput is approximately 160 test results per hour for routine, single reagent chemistries. System throughput will be higher when the test workload includes ISE's. - The instrument has a capacity of 40 reagent containers on board. A reagent cooling system maintains the reagents at 12°C during instrument operation. - Reagent containers are identified by computer coded labels to simplify system operation. All reagents in the system must include an identification label on the container.

- Sample and reagent sensing notify the operator of a depleted condition during operation.
- The system performs analysis at a reaction temperature of 37°C.
- An electrolyte subsystem capable of measuring sodium, potassium and chloride concentrations is included.
- Primary draw tubes may be introduced one at a time into the system for closed tube sampling. Positive tube identification can be achieved with an optional barcode scanner. An aliquot volume sufficient for all tests ordered is transferred and stored and the closed tube is returned to the user.
- Sample cups are introduced to the system one at a time or by sample ring segment.
- Disposable cuvettes are loaded in bulk and then automatically injected as needed by a cuvette hopper system. The ACE Axcel Clinical Chemistry System optical system is capable of monitoring a maximum of 48 cuvettes at one time.
- The absorbance optical system is capable of absorbance measurements in a linear range of 0.0 to 2.0 absorbance units (at 0.67 cm pathlength). Sixteen wavelengths are measured simultaneously using a photodiode array.

The ACE Direct TIBC Reagent is composed of two reagent bottles (Direct TIBC Color Reagent and Direct TIBC Buffer). The Direct TIBC Color Reagent (R1) contains: Chromazurol B, Cetrimide, ferric chloride and
acetate buffer. The Direct TIBC Buffer (R2) contains: sodium bicarbonate buffer.

The ACE Serum Iron Reagent is composed of two reagent bottles (Buffer and Color Reagent). The Buffer (R1) contains: hydroxylamine hydrochloride,
acetate buffer (pH 4.5) and surfactant. The Color Reagent (R2) contains: ferrozine and hydroxylamine hydrochloride.

The ACE Lipase Reagent is composed of two reagent bottles (Lipase Reagent and Lipase Activator Reagent). The Lipase Reagent (R1) contains: 1,2-diglyceride, monoglyceride lipase, glycerol kinase, glycerol-3-phosphate oxidase, N-ethyl-N-(2-hydroxy-3-sulfopropyl)-m-toluidine, ATP, peroxidase and cholic acid. The Lipase Activator Reagent contains: Deoxycholate and 4-Aminoantipyrene.

Performance Data:	Performance data for the Alfa Wassermann ACE Reagents run on the Alfa Wassermann ACE Axcel Clinical Chemistry System included precision, accuracy and detection limit data.
	<u>ACE Direct Total Iron-Binding Capacity (TIBC) Reagent</u>
	<u>Precision</u>: In testing conducted at four TIBC levels for 22 days, the within-run CV ranged from 0.9 to 2.2% and total CV ranged from 2.0 to 3.3%. In precision studies at three separate Physician Office Laboratory (POL) sites over 5 days, the within-run CV ranged from 0.6 to 3.4% and total CV ranged from 0.9 to 4.1%.
	<u>Accuracy</u>: In the correlation study, 109 samples with TIBC values ranging from 96 to 598 µg/dL were assayed on the Alfa Wassermann ACE Axcel Clinical Chemistry System (y) and the Alfa Wassermann ACE Clinical Chemistry System (x). Least squares regression analysis yielded a correlation coefficient of 0.9950, a standard error estimate of 9.1, a confidence interval slope of 0.961 to 0.998 and a confidence interval intercept of -9.2 to 4.3. In patient correlation studies at three separate POL sites, using the Alfa Wassermann ACE Axcel Clinical Chemistry System (y) and the Alfa Wassermann ACE Clinical Chemistry System (x), least-squares regression analysis yielded correlation coefficients of 0.9902 to 0.9987, standard error estimates of 6.1 to 11.2, confidence interval slopes of 0.923 to 1.006 and confidence interval intercepts of -8.2 to 19.4.
	<u>Detection limit</u>: The detection limit was 42.21 µg/dL.
	<u>ACE Serum Iron Reagent</u>
	<u>Precision</u>: In testing conducted at four Serum Iron levels for 22 days, the within-run CV ranged from 1.2 to 5.2% and total CV ranged from 1.3 to 5.4%. In precision studies at three separate Physician Office Laboratory (POL) sites over 5 days, the within-run CV ranged from 1.2 to 4.1% and total CV ranged from 1.2 to 4.2%.
	<u>Accuracy</u>: In the correlation study, 130 samples with Serum Iron values ranging from 13 to 550 µg/dL were assayed on the Alfa Wassermann ACE Axcel Clinical Chemistry System (y) and the Alfa Wassermann ACE Clinical Chemistry System (x). Least squares regression analysis yielded a correlation coefficient of 0.9995, a standard error estimate of 3.3, a confidence interval slope of 1.000 to 1.012 and a confidence interval intercept of -2.7 to -1.0. In patient correlation studies at three separate POL sites, using the Alfa Wassermann ACE Axcel Clinical Chemistry System (y) and the Alfa Wassermann ACE Clinical Chemistry System (x), least-squares regression analysis yielded correlation coefficients of 0.9992 to 0.9998, standard error estimates of 3.0 to 4.9, confidence interval slopes of 0.997 to 1.041 and confidence

	interval intercepts of -2.7 to 9.2.
	Detection limit: The detection limit was 5.08 µg/dL.
	ACE Lipase Reagent
	Precision: In testing conducted at three lipase levels for 22 days, the within-run CV ranged from 1.1 to 6.5% and total CV ranged from 6.2 to 10.7%. In precision studies at three separate Physician Office Laboratory (POL) sites over 5 days, the within-run CV ranged from 0.7 to 7.3% and total CV ranged from 1.9 to 7.3%.
	Accuracy: In the correlation study, 107 samples with lipase values ranging from 15.6 to 697.5 U/L were assayed on the Alfa Wassermann ACE Axcel Clinical Chemistry System (y) and the Alfa Wassermann ACE Clinical Chemistry System (x). Least squares regression analysis yielded a correlation coefficient of 0.9980, a standard error estimate of 9.06, a confidence interval slope of 0.970 to 0.994 and a confidence interval intercept of 1.97 to 5.97. In patient correlation studies at three separate POL sites, using the Alfa Wassermann ACE Axcel Clinical Chemistry System (y) and the Alfa Wassermann ACE Clinical Chemistry System (x), least-squares regression analysis yielded correlation coefficients of 0.9993 to 0.9997, standard error estimates of 4.44 to 7.89, confidence interval slopes of 1.002 to 1.047 and confidence interval intercepts of -4.74 to 3.41.
	Detection limit: The detection limit was 10.63 U/L.
Conclusions:	Based on the foregoing data, the device is safe and effective. These data also indicate substantial equivalence to the predicate device.

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Alfa Wassermann Diagnostic Technologies
c/o Hyman Katz, Ph. D.
Vice President, Quality and Regulatory Affairs
4 Henderson Drive
West Caldwell, NJ 07006

Re: k113438
Trade/Device Name: ACE Direct Total Iron-Binding capacity (TIBC) Reagent, ACE Serum Iron Reagent,
                ACE Lipase Reagent
Regulation Number: 21 CFR §862.1415
Regulation Name: Iron-Binding Capacity Test
Regulatory Class: Class I, reserved
Product Code: JMO, JIY, CHI
Dated: May 21, 2012
Received: May 23, 2012

Dear Dr. Katz:

We have reviewed your Section 510(k) premarket notification of intent to market the device
referenced above and have determined the device is substantially equivalent (for the indications for
use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce
prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that
have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic
Act (Act) that do not require approval of a premarket approval application (PMA). You may,
therefore, market the device, subject to the general controls provisions of the Act. The general
controls provisions of the Act include requirements for annual registration, listing of devices, good
manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it
may be subject to such additional controls. Existing major regulations affecting your device can be
found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may
publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean
that FDA has made a determination that your device complies with other requirements of the Act or
any Federal statutes and regulations administered by other Federal agencies. You must comply
with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part
807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set
forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/Medical Devices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance...

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
    Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

Device Name: ACE Direct Total Iron-Binding Capacity (TIBC) Reagent

Indications for Use: The ACE TIBC Reagent is intended for the quantitative determination of total iron-binding capacity in serum using the ACE Axcel Clinical Chemistry System. Iron-binding capacity measurements are used in the diagnosis and treatment of anemia. This test is intended for use in clinical laboratories or physician office laboratories. For in vitro diagnostic use only.

Device Name: ACE Serum Iron Reagent

Indications for Use: The ACE Serum Iron Reagent is intended for the quantitative determination of iron concentration in serum using the ACE Axcel Clinical Chemistry System. Iron (non-heme) measurements are used in the diagnosis and treatment of diseases such as iron deficiency anemia, hemochromatosis (a disease associated with widespread deposit in the tissues of two iron-containing pigments, hemosiderin and hemofuscin, and characterized by pigmentation of the skin), and chronic renal disease. This test is intended for use in clinical laboratories or physician office laboratories. For in vitro diagnostic use only.

Prescription Use X   AND/OR   Over-The-Counter Use.
(21 CFR Part 801 Subpart D)   (21 CFR Part 801 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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Indications for Use

Device Name: ACE Lipase Reagent

Indications for Use: The ACE Lipase Reagent is intended for the quantitative determination of lipase activity in serum using the ACE Axcel Clinical Chemistry System. Lipase measurements are used in diagnosis and treatment of diseases of the pancreas such as acute pancreatitis and obstruction of the pancreatic duct. This test is intended for use in clinical laboratories or physician office laboratories. For in vitro diagnostic use only.

Prescription Use X   AND/OR   Over-The-Counter Use.
(21 CFR Part 801 Subpart D)   (21 CFR Part 801 Subpart C)

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